Remarks

This Response After Final is in being filed in response to the Final Office Action dated **November 19, 2009.** Reconsideration is requested.

Rejections – 35 U.S.C. §102(b)

The rejection of claims 1-9, 11-30, 53-55, 58-60 under 35 U.S.C. §102(b) as being anticipated by WO 01/78906 (Spillman) has been maintained.

Applicants traverse the rejection.

Claim 1 was previously amended to recite a medical device comprising a multilayer region that comprises a charged nanoparticle layer comprising charged nanoparticles, a plurality of charged polyelectroyte layers comprising charged polyelectrolyte species, *and at least one charged therapeutic agent,* wherein said medical device is configured for implantation or insertion into a subject.

It is asserted in the Final Office Action, Response to Arguments, that:

> Applicant argues that the reference does not properly anticipate the claims because it does not set out "at least one charged therapeutic agent". However in analyzing the claim as written the reference does at least show the inclusion of a drug. The one drug meets the limitation of "at least one". As to its charged nature, the broad term "drug" is inclusive of drugs in their broadest form. As is art recognized, the definition of "drug" often includes derivatives, analogues, and natural and synthetic forms. In its broadest sense, the term "drug" explicitly includes both charged and uncharged derivatives of a drug.
>
> In analyzing anticipation, the first test is whether every structural limitation is explicitly or inherently disclosed in the prior art. As shown above, the term "drug" is inclusive of charged derivatives thereof.
>
> The second part of the analysis is whether the prior art is capable of performing the function. Applicant has not suggested or disclosed any difference in functionality of the charged drug versus uncharged bioactive. As such, the drug set out by the reference is capable of performing the same function as that of the charged

therapeutic.

Final Office Action, Response to Arguments, pp. 3-4

This is not, however, the correct test for anticipation via inherency.

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

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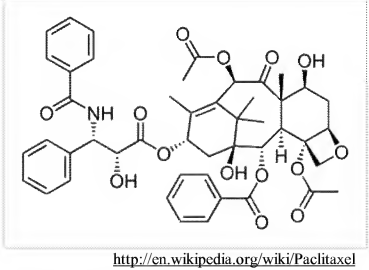
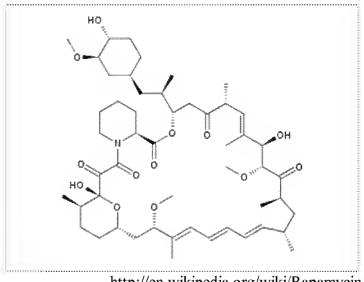
Drugs or therapeutic agents are not necessarily charged species, and in fact, many do not carry a charge. For example, see the formula for Paclitaxel, a drug that commonly employed in cancer treatments and for preventing restenosis:



http://en.wikipedia.org/wiki/Paclitaxel

Likewise the formula for the drug Rapamiycin:



http://en.wikipedia.org/wiki/Rapamycin

While it is true that claim 15 of Spillman (WO 01/78906) does recite "a substrate made biocompatible by a process according to claim 1 *and at least one drug*", there is no disclosure of any specific "drugs" in Spillman, much less any disclosure or suggestion to employ a "charged therapeutic agent" as recited in claim 1. See paragraph [0043].

As drugs are not necessarily charged, there can be no anticipation as a matter of law.

With respect to the assertion that "Applicant has not suggested or disclosed any difference in functionality of the charged drug versus uncharged bioactive," this is clearly incorrect. The use of a charged therapeutic agent with charged layers allows for electrostatic self-assembly of the layers:

> [0017] The multilayer regions of the present invention can be assembled using layer-by- layer techniques. Layer-by-layer techniques can be used to coat a wide variety of substrates using charged materials via electrostatic self-assembly. In the layer-by-layer technique, a first layer having a first surface charge is typically deposited on an underlying substrate, followed by a second layer having a second surface charge that is opposite in sign to the surface charge of the first layer, and so forth. The charge on the outer layer is reversed upon deposition of each

sequential layer.

Furthermore, under 35 U.S.C. §102, Applicants are not required to disclose or suggest any difference in functionality, it is sufficient simply to show that the reference fails to disclose or suggest any feature of the claimed invention.

Withdrawal of the rejection of claims 1-9, 11-30, 53-55, 58-60 under 35 U.S.C. §102(b) as being anticipated by WO 01/78906 (Spillman) is respectfully requested.

CONCLUSION

Claims 1-9, 11-30,53-55 and 58-60 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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